IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the Board of Patent Appeals and Interferences

In re the Application of

Inventor	**:**	**Douglas Roberts et al.**
Application No.	**:**	**10/561,334**
Filed	**:**	**December 15, 2005**
For	**:**	**ELECTRIC- OR MAGNETIC-FIELD BASED DETECTION OF WHEN ELECTRODE PADS HAVE BEEN HANDLED OR REMOVED FROM THEIR PACKAGE**

REPLY BRIEF

On Appeal from Group Art Unit 3766

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This Reply Brief addresses part (10) "Response to Argument" on page 9 of the Examiner's Answer in this appeal.

It is respectfully submitted that a statement in part (10) of the Examiner's Answer focuses the issues in this appeal, from which the Board can proceed to a decision in this appeal. In the middle of page 9 of the Examiner's Answer is the following statement:

> "Lyster also discloses identifying handling of the electrode based on a change in the monitored electrical characteristic (Par. 200 and 259-262)."

It is respectfully submitted that the accuracy of this statement leads to the decision in this appeal, for if it were true then Lyster would be pursuing the same objective as that of the present invention. But if it is not true, then the rejections in this case should be reversed.

The purpose of the Lyster (US 2003/0055478 A1) invention is to sense whether the hydrogel layer of a defibrillator electrode has dried out over time and is therefore unsafe or incapable of delivering a defibrillation shock to a patient. A medical device senses this change in the condition of the electrode hydrogel by measuring the impedance presented by the hydrogel. As stated in paragraph [200] of Lyster

> "As the electrodes' hydrogel layers lose moisture over time, the medical or measuring device may measure a corresponding increase in a real impedance R. ... If the medical or measuring device determines that a temperature compensated real impedance

> value exceeds a given threshold value and/or falls outside an acceptable range, one or more electrode's hydrogel layers may have dried out to an extent that such electrodes 150 are no longer optimal or fit for use."

Paragraph 200 also explains that the impedance measurement is of a complex term characterized by a small, real impedance value R which indicates the hydrogel moisture content, and a larger, imaginary term X which corresponds to the capacitance within the electrode. The problem Lyster then describes is that of discerning the smaller value R in the presence of the much larger and dominant capacitance term. Lyster spends paragraphs [0201] through [0220] describing several ways for extracting the desired R value from the complex measurement dominated by the larger capacitance term. (Earlier in paragraphs [0198]-[0199] Lyster explains that a capacitance value outside a desired range can be an indication of a short, open circuit, or a damaged or defective electrical path in the electrode.)

In paragraphs [0259] - [0260] Lyster describes the embodiment of his Fig. 30, a compartment 3050 with a lid in which defibrillator electrodes may be stored prior to use. Lyster's compartment has an electrical interface 3060 by which the compartment can be plugged into a mating defibrillator. His illustrated compartment has an electrode condition indicator on it, as well as a time remaining indicator. A user or

inspector can observe these indicators and immediately tell whether the condition of the electrodes is good, bad, or intermediate, and how much of the expected lifetime of the electrodes remains. As is well known, electrodes have a shelf life of about one year. For example, US Pat. 6,662,056 (Picardo et al.) states in col. 6, lines 31-37:

> "If the electrode pads 14a and 14b are not properly sealed while packaged and stored, the gel may dry out. This reduces the electrical conduction between the electrode pads and the patient, and thus renders the electrode pads unusable. Therefore, the electrode pads 14a and 14b are typically sealed within the cartridge 46 to insure viability of the gel for a predetermined period, *e.g.*, one year."

In paragraphs [0261]-[0262] Lyster concludes by discussing various configurations of his electrode measurement device, its power sources, and measurement computation, and placement of the indicators on the measurement device.

It is apparent from the foregoing that Lyster is describing the measurement of the progress of a long-term phenomenon, the drying out of electrode hydrogel over a period of a year or more. Paragraphs [0200] and [0259]-[0262] give no indication that handling the electrodes has any noticeable effect on hydrogel drying. If the lid of the compartment is opened and the electrodes taken out, is there a discernible change in the hydrogel's moisture content? If the electrodes are then handled for a minute or an hour or a day, is there then a change? The answer is

obviously no, as handling has no discernible effect on the hydrogel drying and even the day-long period is but one 365th of the expected lifetime being measured. There is nothing in any of the passages cited by the Examiner's Answer that would lead one to conclude that Lyster's measurement of the moisture content of electrode hydrogel would be any indication of the handling of an electrode. As the present claims make clear, it is a change in the capacitance existing between a conductor attached to the electrode compartment and the electronic components of the electrodes when the electrodes are removed from the compartment that the present invention uses as an indicator of electrode removal or handling. The slowly changing resistance of drying hydrogel is wholly inadequate for this purpose.

The secondary references applied are directed at finer points, such as the use of a.c. current in monitoring impedance (Pihl et al.) and frequency-shift monitoring (Thu et al.) Accordingly it is respectfully requested that this Honorable Board reverse the rejection of Claims 1-20 in the present application.

Respectfully submitted,

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